Remarks

I. The Office Action

The February 19, 2009 non-Final Office Action (the "Office Action") in this application:

1. provisionally rejects claims 1, 9-10, 13-19 and 29 under the doctrine of obviousness-type double patenting;

2. rejects claims 1-3, 10-17, 19-20 and 29 under 35 U.S.C. 102(a);

3. rejects claims 1-20 and 29 102(b);and

4. rejects claims 1-20 and 29 under 102(b).

Applicants respond as follows.

Applicants have amended independent Claims 1, 9, and 16.

II. Claim Amendments

The Applicants have amended independent Claims 1, 9, and 16 to now positively recite that the botulinum toxin is a pure botulinum toxin (i.e. not a botulinum toxin complex), wherein the pure botulinum toxin has a molecular weight of about 150 kDa. Support for this amendment can be found, for example, at least at page 27, lines 23-25 and at page 28, lines 26-27 of the specification.

III. Provisional Obviousness-type Double Patenting rejection of claims 1, 9-10, 13-19 and 29

The Office Action has maintained its provisional rejection of claims 1, 9-10, 13-19 and 29, under the judicially created doctrine of obviousness-type double patenting, over claims 1-3, 5-12 and 14-17 of co-pending Application No. 11/039,506. Applicants respectfully traverse this rejection.

Independent claims 1, 9, and 16 of the instant application have been amended to recite the administration of pure botulinum toxin, whereas the claims in U.S. App. No. 11/039,506 do not recite such limitations. Respectfully, the Office Action's discussion relating to scope of the subject claims is not the method by with obviousness-type double patenting rejections are made, and Applicants respectfully request that this rejection be withdrawn.

IV. Rejection of claims 1, 3 10-17, 19-20 and 29 under 35 U.S.C. 102(a)

The Office Action has rejected claims 1-3, 10-17, 19-20, and 29 under 35 USC 102(a) as being anticipated by Schim (*Current Medical Research and Opinion*, Vol. 20, No.1, pp. 49-53, 2004). The Applicants respectfully traverse this rejection.

Solely and in order to expedite prosecution only, Applicants have amended all independent Claims 1, 9, and 16 to recite that the botulinum toxin administered is a pure botulinum toxin, in particular, having a molecular weight of about 150 kDa. This is an additional limitation, in addition to the previously recited limitation that the acute pain medication is taken by the patient prior to experiencing pain, and experiences pain after the intake of acute pain medication.

As previously asserted, Schim does disclose or render obvious the present claims. While Schim discusses how "reducing the frequency and/or severity of migraine attacks could decrease the need for acute headache medication,", Schim does not address the needs of patients that take medication in anticipation of, rather than in response to, a headache, let alone the administration of a pure botulinum toxin, in particular, having a molecular weight of about 150 kDa, as presently claimed.

Since Schim does not describe each and every element of the present claims, Schim cannot anticipate the instant claims. Thus, Applicants respectfully request withdrawal of this rejection.

V. Rejection of claims 1-20 and 29 under 35 U.S.C. 102(a)

The Office Action has rejected claims 1-20 and 29 under 35 USC 102(b) as anticipated by Tepper et al. (*Cephalalgia*, Vol. 23, pp. 581-762, 2003). The Applicants respectfully traverse this rejection.

As discussed above, independent claims 1, 9, and 16 now recite the limitation that the botulinum toxin administered is a pure botulinum toxin, in particular, having a molecular weight of about 150 kDa, in addition to the previously discussed limitations of preemptive use of an acute pain medication. As previously presented in earlier replies to previous Office Actions, the preemptive use of medication is not associated with an actual pain or ache. Tepper et al. do not even hint at the efficacy of botulinum toxin for treating the pre-emptive use of pain medication, let alone specifies that the botulinum toxin administered is a pure botulinum toxin, in particular, having a molecular weight of about 150 kDa. A skilled artisan in view of Tepper et al. actually may be lead to believe that medication overuse leads to reductions in headache frequency since Tepper's figure shows there is a lower occurrence of headache in medication "overusers" than "non-overusers" at baseline. The present claims, however, are directed to treating the taking of medication before pain is experienced, and administration of a pure botulinum toxin having a molecular weight of about 150 kDa. Since Tepper et al. do not describe each and every element of the present claims, does not lead a skilled artisan to the present claims, Tepper et al. cannot anticipate the instant claims. Thus, Applicants respectfully request withdrawal of this rejection.

VI. Rejection of claims 1-20 and 29 under 35 U.S.C. 102(a)

The Office Action rejects claims 1-20 and 29 under 35 USC 102(b) as anticipated by Mathew et al. (*Headache*, 2002, Vol. 42, p. 454; Abstract S107). Applicants respectfully traverse this rejection.

As previously asserted, Applicants have amended independent Claims 1, 9, and 16 (and thus all pending claims) to recite that the botulinum toxin administered is a pure

botulinum toxin, in particular, having a molecular weight of about 150 kDa, in addition to the additional limitations of the claims (e.g. preemptive use of acute pain medication). Similar to Schim and Tepper et al. , Mathew et al. do disclose or render obvious the present claims, but rather Mathew et al. disclose that "patients had poor headache control, poor quality of life . . . and high acute medication intake in spite of detoxification from analgesics and appropriate prophylactic therapy." Mathew et al. conclude that "Botulinum toxin type A in selected patients with chronic migraine appears to modify the disorder, reducing the disability and acute medication use." As previously asserted, ordinary acute medication use (e.g. taking the medication because the patient is experiencing a pain) is not the same as the pre-emptive use of medication before pain is experienced, in accordance with the present claims. In fact, Mathew et al. never mention pre-emptive use of medication. Accordingly, since Mathew et al. do not describe each and every element of the present claims and cannot lead a skilled artisan to the present claims, this reference cannot anticipate the instant claims. Thus, Applicants respectfully request withdrawal of this rejection.

V. Conclusion

All issues raised in the Office Action have been addressed. Reconsideration and allowance of claims 1-20 and 29 is requested.

Applicants respectfully requests that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with entry of this Amendment to deposit account No. 01-0885.

Respectfully submitted,

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